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32.

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(New) A composition according to claim 1 which further comprises, in the second component, a compound which is capable of being converted into the substrate for the galactose oxidase.

REMARKS

I. ABSTRACT OF THE DISCLOSURE IS ATTACHED ON A SEPARATE SHEET.

It was stated that the application lacks an Abstract of the disclosure as required by 37 C.F.R. § 1.72(b). It was Applicants' understanding that Abstract of the PCT application (PCT/DK98/090335), which forms the basis for this U.S. application, was included in the application.

Nonetheless, Applicants have included, on a separate sheet, attached hereto as Appendix C an Abstract of their disclosure.

II. CLAIM AMENDMENTS AND NEW CLAIMS

Some claims have been amended, support for the amendments being found in the specification, considered as a whole. For example, claims 19-23 are amended to place them in a form more commonly accepted in U.S. patent practice. The amendments of claims 19-23 are not related to reasons for patentability.

New claims 24-31 are directed to additional details of the invention, support therefor being found at pages 7-9.

III. CLAIMS 1-25 ARE DEFINITE

Claims 1-25 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failure to particularly point out and distinctly claim subject matter regarded by Applicants as their invention. It was stated that the use of the term "and/or" in claim 1 rendered these claims indefinite. In particular, it was elaborated that it was not understood how a composition can contain an enzyme, its substrate and the enzyme which made the first enzyme's substrate, and it was inquired why one

would need the enzyme which makes galactose if galactose is already present to react with galactose oxidase. Office Action, page 2.

Applicants respectfully traverse this rejection.

It is well established that claims are definite under 35 U.S.C. § 112, second paragraph, if, read in the light of the specification, they reasonably apprise persons skilled in the art of the utilization and scope of the invention. *Andrew Corp. v. Gabriel Electronics Inc.*, 6 USPQ2d 2010 (Fed. Cir. 1988) and cases cited therein. The criticized phrase, read in light of the specification, means that the claimed composition includes, as a second component: (i) an oxidizable substrate for the galactose oxidase; (ii) an enzyme capable of converting a compound into a substrate for the galactose oxidase; or (iii) the combination of the oxidizable substrate and the enzyme capable of converting a compound into a substrate for the galactose oxidase. Persons of ordinary skill in the art would be reasonably apprised of the utilization and the scope of the invention of such a claim, and therefore would readily understand the metes and bounds of the protection sought by Applicants.

It is well known that in order to achieve a maximum effect of an enzyme under given conditions, a sufficient amount of a substrate must be available. The Applicants fail to see any possible contradiction in the term "and/or", as the effect of the galactose oxidase will be achieved when there is sufficient available oxidizable substrate for the enzyme. The provision of a sufficient amount of a substrate can be achieved by (i) adding a substrate directly, (ii) adding a further enzyme that is capable of converting a compound, e.g., hemicellulose compounds, into a compound that is oxidizable by the galactose oxidase (i.e., a substrate for the enzyme), or (iii) by adding both a substrate directly and an enzyme capable of generating a substrate. It is submitted that the term "oxidizable structure" does not imply that a better effect could not be achieved by combining a certain, but possibly suboptimal, amount of a substrate with a second enzyme that in a suitable environment, e.g., a dough, can generate a further oxidizable substrate for the galactose oxidase.

a dough is
not an enzyme

IV. CLAIMS 1, 2, 4-10, 13-17, 20, 21, AND 23 ARE NOVEL IN VIEW OF SOMERS BECAUSE SOMERS FAILS TO DISCLOSE AN OXIDIZABLE SUBSTRATE FOR GALACTOSE OXIDASE OTHER THAN GALACTOSE

Claims 1, 2, 4-10, 13-17, 20, 21, and 23 were rejected under 35 U.S.C. § 102(b) as anticipated by Somers *et al.*, Cereal Food World, July 1996, volume 41, No. 7, page 550 ("Somers" or "Somers *et al.*"). Applicants respectfully traverse this rejection.

Somers teaches the use of galactose oxidase and galactose in dough making. It is apparent that Somers specifically recites "galactose" as the substrate for the galactose oxidase. Applicants' aforementioned claims, which now exclude galactose in at least one embodiment, are novel in view of Somers.

V. CLAIMS 1-25 ARE PATENTABLE OVER SOMERS IN VIEW OF WO 96/39851, BANKS ET AL. AND CLARK, JR. BECAUSE THE COMBINATION OF THE REFERENCES IS IMPROPER. THE COMBINATION, EVEN IF PROPER, WOULD NOT HAVE RENDERED OBVIOUS APPLICANTS' CLAIMS. EVIDENCE OF UNEXPECTED RESULTS UNDERSCORES PATENTABILITY OF THESE CLAIMS.

Claims 1-25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Somers in view of WO 96/39851 (hereinafter '96), Banks et al., U.S. Patent 4,828,853 and Clark, Jr., U.S. Patent 4,458,686. It was acknowledged that Somers fails to disclose that an enzyme, such as a hemicellulase, is specifically used with the galactose oxidase, that lactose could be the substrate for the galactose oxidase, that the galactose oxidase can originate from a plant, fungi or bacterial species, or that the dough can be noodle or alimentary paste dough. The disclosure of '96 was relied upon for its teaching of the addition of an oxidoreductase capable of oxidizing maltose and of other enzymes that can be added to the oxidoreductase. Such other enzymes, according to the Office Action, are exemplified by cellulases, hemicellulases, xylanases, glucose oxidase, and they are added to improve the dough. The teaching in '96 that the dough can be a noodle or an alimentary paste dough was also relied upon. Office Action, page 4.

Banks was cited for its disclosure that dough compositions can contain sugars, such as lactose or galactose, and Clark for its teaching that galactose oxidase is commonly derived from microorganisms, such as *Dactylium dendroides*.

It was suggested that it would have been obvious to add hemicellulases into the composition of Somers because both Somers and '96 teach the use of these enzymes as dough improving agents, and all enzymes are expected to increase dough improvement. It was also alleged that the use of noodle or alimentary dough would have been obvious in view of the teaching of '96 and the combination of Banks and Clark would have rendered obvious the use of lactose in place of galactose as a substrate for galactose oxidase. Office Action pages 4-5.

The disclosure of Clark was additionally relied upon as allegedly making it obvious to derive galactose oxidase from a microorganism, such as a plant, fungi or bacteria and further in view of the teaching of '96 which isolates their enzyme from algae. It was additionally alleged that it is well known in the art that enzymes from microorganisms have many beneficial properties over non-microorganism derived enzymes. Office Action, pages 4-5.

Clark
teaches
equivalency
between
galactose
&
lactose

Applicants respectfully traverse this rejection.

Before discussing in detail the rejection, Applicants wish to summarize their claimed invention. Applicants discovered their invention in the context of the knowledge in prior art of the use of hemicellulases to obtain improved bread quality. Nonetheless, it was also known that the use of such bread improving additives in otherwise desirable high amounts produces undesirable side effects, as the dough becomes too slack and sticky. The inventors discovered that these adverse effects of hemicellulases can be reduced significantly by combining these enzymes with an effective amount of galactose oxidase and a substrate for this enzyme, other than galactose as such, which in turn permits the bread improving hemicellulases, when combined with galactose oxidase, to be added at higher amounts than when they were used without galactose oxidase.

Thus, Applicants' claims are directed to a composition comprising two components. The first component is a galactose oxidase, and a second component is an oxidizable substrate, other than galactose, for the galactose oxidase, an enzyme which is capable of converting a compound into a substrate for the galactose oxidase or a combination of the oxidizable substrate and the enzyme. The invention is also directed

to a method of preparing the flour dough with the Applicants' composition and to a method of using such a composition.

It is well established that to present a *prima facie* case of obviousness, three basic criteria must be met:

1. there must be a suggestion or motivation, in the references or in the knowledge generally available to persons of ordinary skill in the art, to modify a particular reference or to combine teachings of various references;
2. there must be a reasonable expectation of success;
3. The prior art reference (or references when combined) must teach or suggest every claim limitation.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art and may not be based on Applicants' disclosure. E.g., see *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The rejection based on the combination of Somers, '96, Banks et al., and Clark, Jr. does not satisfy the above criteria and is therefore erroneous as a matter of law. There is simply no suggestion, much less disclosure, in the four corners of '96 to selectively pick the disclosure of an enzyme (other than oxidoreductase, such as hexose oxidase) from the text of '96, and combine it with Somers. Similarly, there is no suggestion or motivation found in the prior art of record, or identified by the Examiner as having been found in the knowledge of persons of ordinary skill, to pick the disclosure of lactose or galactose from Banks et al. and of a microorganism-based galactose oxidase from Clark, Jr. and combine those with Somers and '96. Such improper combinations could only have been made with the benefit of hindsight provided by Applicants' own invention which, of course, is impermissible. There is also no suggestion (much less teaching) in the prior art of a reasonable expectation of success of such combinations improving properties of the dough.

Even if, *arguendo*, the combination were proper, it would have failed to establish *prima facie* case of obviousness. The combination, at best, would have been directed to a

composition comprising galactose oxidase, galactose as a substrate for the galactose oxidase, other enzymes, such as hemicellulase, xylanase, cellulase, a starch degrading enzyme, a glucose oxidase, a lipase, and a protease (disclosed in '96). Since such an improper combination would have comprised galactose (or "monomeric galactose") as the only substrate for galactose oxidase, it would not have rendered obvious the claimed invention wherein galactose is specifically excluded as a substrate in at least one claimed embodiment.

Even if, *arguendo*, *prima facie* case was established, it is rebutted by evidence of unexpected results in the application.

As disclosed in Applicants' specification, the Applicants tested monomeric galactose as a substrate for galactose oxidase in comparison with di-galactose and arabinogalactan treated with arabinofuranosidase (which is believed to include a poly-galactose or oligomer of galactose (Example 2 and Fig. 4)). The quite surprising result of these experiments was that monomeric galactose was a much poorer substrate for the galactose oxidase than were the other galactose-containing compounds. nice,
but,
nothing to
do w/
refs.

Therefore, the unexpected improvement achieved by adding galactose oxidase in the presence of an oxidizable substrate therefor (other than galactose) was discovered by Applicants, which is not suggested in and which cannot be derived from any of the aforementioned references, either taken alone or in combination.

The evidence of unexpected results underscores the fact that the effect of galactose oxidase in reducing the adverse effects on the dough quality of the addition of hemicellulases was completely unknown in the art at the time Applicants made their invention.

Applicants traverse the assertion that all "... of the enzymes are expected to increase improving dough ..." (Office Action, page 4). (Applicants understand this statement to mean that all enzymes are expected to improve dough properties). If Applicants' understanding is correct, this assertion is not supported by any art of record, nor by any other evidence cited by the Examiner. In fact, the evidence of unexpected results (discussed herein) underscores the lack of predictability of actions of various enzymes on different substrates.

For all of the above reasons, withdrawal of this rejection is solicited.

VI. CLAIMS 1-25 ARE UNOBVIOUS AND PATENTABLE OVER SOMERS IN VIEW OF WO 94/28728, BANKS *ET AL.*, CLARKE, JR., GILLMORE *ET AL.*, AND YOKOTSUKA *ET AL.* BECAUSE THE COMBINATION IS IMPROPER. EVIDENCE OF UNEXPECTED RESULTS REBUT ANY POSSIBLE PRIMA FACIE OBVIOUSNESS OF THE IMPROPER COMBINATION OF REFERENCES.

Claims 1-25 were rejected as obvious under 35 U.S.C. § 103 over Somers, in view of WO 94/28728 (hereinafter '94), Banks et al., Clark, Jr., Gillmore *et al.*, U.S. Patent 5,063,072, and Yokotsuka *et al.*, U.S. Patent 4,820,520. The teaching of Somers, Banks et al. and Clark, Jr. were relied upon for the same reasons as discussed above.

The disclosure of '94 was relied upon for its teaching of the addition of a laccase to dough and other baked products to improve their properties. It was also relied upon for its teaching that other enzymes may be used with laccase, such as cellulases, hemicellulases, pentosanases, glucose oxidase, lipase, protease and alpha-amylase. Office Action, page 5.

Gillmore was cited for its apparent teaching that the alimentary paste and dough are the same and Yokotsuka for its disclosure that noodle dough is routinely used in dough making. Office Action, page 6.

It was concluded that it would have been obvious to add hemicellulases in the composition of Somers since both Somers and '94 teach that the enzymes are used as dough improving agents and all enzymes are expected to improve dough. Office Action, page 6. It was also stated that the use of noodle or alimentary dough would have been obvious in view of the teachings of Gillmore and Yokotsuka, and it would be obvious to use lactose instead of galactose as a substrate for galactose oxidase in view of the teachings of Banks et al. and Clark, Jr. Office Action, page 6. It was additionally concluded that Clark, Jr.'s disclosure would have made it obvious to derive the galactose oxidase from a microorganism, such as a plant, fungi or bacteria. It was further asserted that it is well known in the art that microorganism-derived enzymes have beneficial properties as compared to non- microorganisms derived enzymes. Office Action, pages 6-7.

Applicants traverse this rejection. Initially, Applicants respectfully reiterate their traversal of the assertion that all enzymes are expected to improve dough. This assertion is unsupported by art of record nor any other evidence cited in the Office Action, as discussed above. *Really!*

Furthermore, as with the first obviousness rejection discussed above, the combination of the references in this obviousness rejection is improper as a matter of law. There is simply no motivation or suggestion within any of the six references used to reject claims 1-25 to combine the teachings thereof, much less to pick individual, isolated portions of some references and combine them with other, individual, isolated portions of different references. Such a combination of various selectively-chosen portions could only have been made with the improper benefit of hindsight based on Applicants' own disclosure.

Even the improper combination would not have suggested to persons skilled in the art Applicants' claimed invention. For example, such a combination would not have suggested the use of an oxidizable substrate for galactose oxidase, which is not monomer galactose, alone as an oxidizable substrate, or in combination with an enzyme capable of converting a compound into a substrate for the galactose oxidase. In fact, the references teach away from the use of a substrate other than galactose monomer because Somers (the primary reference) specifically and explicitly refers to galactose as the only substrate disclosed by him.

For all of the above reasons, the improper combination of the references fails to establish a *prima facie* case of obviousness.

Even if, *arguendo*, such a *prima facie* case were established, it is effectively rebutted by the evidence of unexpected results, discussed above.

VII. REQUEST FOR ALLOWANCE.

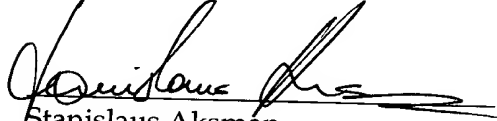
In view of all the arguments set forth above, an indication of allowance of all claims is solicited.

Respectfully submitted,

HUNTON & WILLIAMS

Date: May 31, 2001

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APPENDIX A

Cereal flour has a natural[ly] content of non-starch polysaccharides comprising galactose moieties as structural elements, in particular hemicellulose compounds, including compounds which are generally referred in the art as pentosans or xylans. It was found that such structural components hereof are useful substrates for galactose oxidase.

Using the method described in [3.1] 4.1, the effect on the specific volume and stickiness of P70 (250 μ l/kg flour) and galactose oxidase (150 U/kg flour) was tested during 8 different flours. The results are shown in table 4.2 below.

APPENDIX B

1. (Once Amended) A composition comprising₂ as a first component₂ a galactose oxidase (EC 1.1.3.9) and₂ as a second component₂ an oxidizable substrate for the galactose oxidase, other than galactose, and/or an enzyme which is capable of converting a compound into a substrate for the galactose oxidase.
9. (Once Amended) A composition according to claim 8 wherein the oxidizable substrate compound [is selected from the group consisting of] comprises a galactan, a galactose oligomer or a galactose dimer[, or galactose].
17. (Once Amended) A method according to claim 16₂ wherein the flour dough is an alimentary paste dough.
19. (Once Amended) [Use] A method of using the composition of claim 1 [as a dough and/or bread improving agent.], comprising adding the composition to dough ingredients, dough additives, a dough or a combination thereof.
20. (Once Amended) [Use] A method according to claim 19₂ wherein the composition comprises a further enzyme component [selected from the group consisting of] which includes a cellulase, a starch degrading enzyme, a lipase [and] or a protease.
21. (Once Amended) [Use] A method according to claim 19 or 20₂ wherein the composition [is one] further [comprising] comprises a non-enzymic dough additive compound.
22. (Once Amended) [Use] A method according to claim 19 or 20₂ wherein the galactose oxidase [is] added to the dough ingredients, dough additives or the dough [in the form of a preparation] is substantially [not containing] free of other enzyme activities.
23. (Once Amended) [Use] A method according to claim 19₂ wherein the galactose oxidase is [provided in] the form of a crude enzyme preparation.

APPENDIX C

ABSTRACT OF THE DISCLOSURE

A dough and bread improving composition comprising an enzyme having galactose oxidase activity and an oxidizable substrate for this enzyme and/or an enzyme which is capable of converting a compound, e.g., a galactose-containing compound, into a substrate for the enzyme having galactose oxidase activity.